Message

From: Niman, Aaron [niman.aaron@epa.gov]

Sent: 4/9/2020 12:12:31 PM

To: Miller, David [Miller.DavidJ@epa.gov]

CC: Maratos, Marie - OSEC, Washington, DC [marie.maratos@usda.gov]

Subject: FW: Reply needed by 15 April: Outreach on 2021 Extraordinary JMPR

Attachments: image002.jpg; ATT00001.htm; ATT00001.txt; ATT00002.htm; Imazalil additional use nomination 2021.xlsx;

ATT00003.htm; CCPR51 final report REP19_PRe.pdf; ATT00004.htm

See the forwarded email below. This is from Jannsen which indicated that it would provide citrus data for Imazalil at the last CCPR.

From: Ray McAllister < RMcAllister@croplifeamerica.org>

Sent: Thursday, April 9, 2020 7:56 AM **To:** Niman, Aaron <niman.aaron@epa.gov>

Subject: Fwd: Reply needed by 15 April: Outreach on 2021 Extraordinary JMPR

FYI

Ray S. McAllister, Ph.D.
Senior Director, Regulatory Policy
CropLife America
202-872-3874 (office)
202-577-6657 (mobile)
ray@croplife.us

Begin forwarded message:

From: "Douaiher, Marie Noelle [JRDBE]" < MDOUAIHE@its.jnj.com>

Date: April 9, 2020 at 6:43:50 AM EDT

To: Ray McAllister < RMcAllister@croplifeamerica.org Cc: "Goodwine, Bill [JANUS]" BGoodwine (a) Linitation Linitation RMCAllister@croplifeamerica.org Cc: "Goodwine, Bill [JANUS]" Linitation

Subject: FW: Reply needed by 15 April: Outreach on 2021 Extraordinary JMPR

Good morning,

Hope you are doing well, and that things are well during these unusual period we are living in.

Please find below Janssen PMP reponses to the questions received through CropLife EU.

1. Are there any registrant concerns about focusing the meeting on <u>new uses</u>, as was done in the Extraordinary Session held in Ottawa in spring, 2019?

[[MND]] Janssen is planning to submit the dossier this upcoming fall, for the imazalil uses on grapefruit and mandarins (as per the attached excel) for evaluation. This submission is referenced in the final CCPR51 published docs - pdf attached point 65.

2. Is a fall timeline feasible for your dossier preparation and submission timeline to JMPR? An October dossier submission deadline is being discussed as a possibility (but it is not final). There is urgency in completing the extraordinary JMPR session before the end of CY2021 for the US Government (December 31, 2021), because of constraints on availability of funding.

[[MND]] Yes timelines seem to be feasible for Janssen.it would be preferable to receive a pre-notice about the submission deadline, in order to avoid surprises.

3. We need to know what new uses (AI and crops) registrants would pursue if offered the opportunity to submit a dossier to the extraordinary meeting. Can you identify compounds that can be prioritized from the existing CCPR Schedule/Priority List? Are there other compounds that are not listed, but could be added if there is capacity for review?

[[MND]] yes, Imazalil for grapefruit and mandarins (as the attached excel)

Please let me know if any clarifications are needed, and also, can you please confirm the receipt of this mail.

Stay safe. Best wishes,

Dr Marie-Noêlle Douaiher